IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: All Cases Listed in Exhibit A to Motion	

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO MOTION OF ACTAVIS, INC., ACTAVIS PHARMA, INC., ACTAVIS LABORATORIES UT, INC., WATSON LABORATORIES, INC., ANDA, INC., AUXILIUM PHARMACEUTICALS, INC., PFIZER INC., AND PHARMACIA & UPJOHN COMPANY LLC TO DISMISS AND FOR JUDGMENT ON THE PLEADINGS PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 12(B)(6) AND 12(C)

June 15, 2015

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Statutes, Rules, and Regulations

Other Authorities

INTRODUCTION

In their motion to dismiss, Defendants Actavis, Inc., Actavis Pharma, Inc., Actavis Laboratories UT, Inc., Watson Laboratories, Inc., Anda, Inc., Auxilium Pharmaceuticals, Inc., Pfizer Inc., and Pharmacia & Upjohn Company LLC ("Moving Defendants") contend that because their products were approved through an "abbreviated new drug application" ("ANDA"), Plaintiffs' claims against them are preempted by the federal Food, Drug, & Cosmetic Act ("FDCA"). Defendants are wrong: because their products are listed by the federal Food & Drug Administration as "reference listed drugs" ("RLD"),[1] there is no federal preemption. Defendants' argument to the contrary is based on misreading applicable federal precedents and ignoring entirely the actual federal regulations that underlie those precedents.

In *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Supreme Court held that, where a generic manufacturer is precluded from making unilateral changes to the drug label, claims against the manufacturer for failure to warn are preempted by FDCA. The Moving Defendants would have this Court mindlessly apply *Mensing* to preempt Plaintiffs' claims here, but examination of the actual holding in *Mensing*, and the basis for it, shows that failure-to-warn claims are not preempted where the defendant's product at issue is an RLD. In *Mensing*, the Court found that the generic

[1] Pfizer, Inc. and Pharmacia & Upjohn Company LLC (the "Pfizer Defendants") move in connection with their testosterone replacement therapy ("TRT") product Depo-Testosterone, *see* Moving Defendants Request for Judicial Notice ("Def. RJN") at ¶ 2, which, as discussed below, is the reference listed drug for 100 mg and 200 mg testosterone cypionate injections. Auxilium Pharmaceuticals, Inc. ("Auxilium") moves in connection with its TRT product Testopel, *see* Def. RJN at ¶ 2, which, as discussed below, is the reference listed drug for 75 mg testosterone pellets. The remainder of the moving defendants (the "Actavis Defendants") move in connection with their unbranded generic products, *see* Def. RJN at ¶ 2. As of June 12, 2015, however, every claim against the Actavis Defendants involving a generic TRT product has been dismissed voluntarily by the plaintiff. *See* Exhibit A hereto. (The Actavis Defendants are also sued in connection with their TRT product, Androderm, *see* Second Amended Master Long-Form Complaint ¶ 56, which is not a generic drug and was approved pursuant to a New Drug Application, rather than an ANDA. The motion to dismiss is not addressed to claims involving Androderm.) Accordingly, the only issue pertaining to the Actavis Defendants raised by the motion pertains to the sufficiency of Plaintiffs' allegations against them. *See* Point III, *infra*. The preemption issues the Moving Defendants raise pertain only to the Pfizer Defendants and Auxilium.

manufacturer was precluded from changing the label because FDA regulations required that the generic label at issue be identical to the branded label. It was, therefore, impossible for the generic manufacturer to comply with both state law duties to warn – which required it to add warnings beyond those in the FDA-approved label – and federal law duties to keep its label identical to the label approved by the FDA for the branded drug. This impossibility was the sole basis for preemption in *Mensing*; indeed, in *Wyeth v. Levine,* 555 U.S. 555 (2009), the Supreme Court had found failure-to-warn claims against a branded manufacturer *not* preempted because the branded manufacturer in that case was not precluded from making unilateral changes to the label. Comparison of *Mensing* and *Levine* demonstrates beyond doubt that federal preemption for failure to warn claims turns on whether, under the federal regulatory scheme, a manufacturer is permitted to make unilateral changes to the drug label. If it may do so, there is no preemption, because the manufacturer can comply with both its state and federal law duties.

The key fact here is that the FDA regulations that precluded the generic manufacturer in *Mensing* from making unilateral changes to the label do *not* preclude the owner of the RLD from making such changes. That is because the regulations do not require a generic label to be the same as a branded label; nor do they make use of the distinction between drugs approved through a New Drug Application ("NDA") and those approved through an ANDA, the terminology on which the Moving Defendants focus. Rather, the actual language of the regulations speaks only in terms of the reference listed drug: they require only that a generic label be identical to the label for the reference listed drug. Where a particular generic *is* the reference listed drug, unilateral changes to the label will not result in a discrepancy between the label for that particular generic and the label for the listed drug and the RLD holder is free to make such changes as it believes are necessary, as its label will always, by definition, be identical to the label for the RLD.

Because these regulations do not restrict the ability of the RLD holder to make changes to its label, it is not impossible for the RLD holder to comply with both state and federal law duties. And because this Court can take judicial notice that each of the Moving Defendants' testosterone replacement therapy ("TRT") product is a reference listed drug, the motion to dismiss should be

denied in its entirety. In the alternative, the motion should be denied because Plaintiffs should be given the opportunity to establish, through discovery, that RLD holdings, including the Pfizer Defendants' predecessor, have in fact made unilateral changes to the labels for their TRT products.[2]

LEGAL STANDARD

On a motion to dismiss under Rule 12(b)(6), the Court "construe[s] the complaint in the light most favorable to the plaintiff, taking as true all well-pleaded factual allegations and making all possible inferences from those allegations in his or her favor." *Wilson v. Price*, 624 F.3d 389, 391 (7th Cir. 2010). Thus, dismissal is proper only where "it appears beyond doubt that the plaintiff cannot prove any facts that would support his claim for relief." *Wilson*, 624 F.3d at 392.

ARGUMENT

I. PLAINTIFFS' CLAIMS ARE NOT PREEMPTED BECAUSE DEFENDANTS' PRODUCTS ARE "REFERENCE LISTED DRUGS"

The Moving Defendants claim that, under *Mensing*, Plaintiffs' claims are preempted because each of the Moving Defendants' TRT products was approved pursuant to an ANDA. But the mechanism by which a drug is approved is not determinative of the preemption question. Rather, the question for the Court is whether federal law or regulations prevent the Moving Defendants from providing the warnings Plaintiffs say should have been provided. As discussed below, because the Moving Defendants' products are RLDs for other similar generics, *no* federal law or regulation interferes with the Moving Defendants' ability to provide the warnings necessary to satisfy the requirements of state tort law. For this reason, *Mensing* does not call for preemption of Plaintiffs' claims here.

The cornerstone of *Mensing* preemption was the Court's finding in that case that it would have been impossible for the defendant generic drug manufacturer to comply with both FDA labeling regulations and state-law failure to warn duties. As the Court explained:

[2] The Actavis Defendants separately argue that the allegations concerning off-label promotion and marketing against them are insufficient. As demonstrated below, however, these allegations are sufficient to pass muster at the pleading stage.

> We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. . . . *If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law.*

131 S. Ct. at 2577-78 (emphasis added). This holding contrasts with the holding in *Levine*, where the Court found that the defendant drug manufacturer "failed to demonstrate that it was impossible for it to comply with both federal and state requirements." This was because FDA regulations "permitted Wyeth to unilaterally strengthen its warning. . . ." 555 U.S. at 573. Thus, the question whether *Mensing* or *Levine* governs here requires examination of the applicable FDA regulations to determine whether the Moving Defendants here were precluded from making unilateral changes to the labels for their TRT products. As we now show, for products identified by the FDA as the RLD – that is, for each of the Moving Defendants' products -- it is clear there is no such prohibition.

A. FDA Regulations Do Not Preclude an RLD Holder from Making Unilateral Changes to the Label

1. FDA Regulations Define "Listed Drugs" and "Reference Listed Drugs"

The Moving Defendants' motion is based on the distinction between a drug approved pursuant to an NDA and one approved pursuant to an ANDA. An NDA requires a comprehensive submission allowing the FDA to determine that the proposed drug is safe and effective. *See* 21 U.S.C. § 355(b). An ANDA requires the applicant to show that the proposed drug is equivalent to an existing drug that has already been approved; based on this showing, an ANDA need not be accompanied by the same kind of comprehensive submission as an NDA, because the drug is, in essence, a "duplicate" of a drug that has already been approved. 21 U.S.C. § 355(j). But although the distinction between an NDA and an ANDA is of critical importance to the process of obtaining drug approval, it is not the relevant distinction with respect to labeling. Similarly, although in common parlance, the term "branded drug" is typically used to refer to a drug approved pursuant to an NDA, while "generic drug" is used to refer to a drug approved pursuant to an ANDA, this terminology is not also relevant to the requirements for drug labeling.[3] Rather, the critical

[3] Plaintiffs note, however, that both Depo-Testosterone and Testopel are branded drugs; their designations are brand names that distinguish them from generic versions of 100 mg and 200 mg (footnote continues on next page)

distinction for purposes of drug labeling is between a "reference listed drug" or RLD, on the one hand, and generic copies approved with reference to that particular RLD, on the other.

As part of the Hatch-Waxman Act, in 1984, Congress requires the FDA to "publish and make available to the public . . . a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section. . . ." 21 U.S.C. § 355(j)(7)(A)(i). The original list was required to be published within 60 days of September 24, 1984. Thereafter, the statute requires that "[e]very thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness . . . during the thirty-day period." 21 U.S.C. § 355(j)(7)(A)(ii). The FDA defines drugs on this list as "listed drugs." 21 C.F.R. § 314.3.

In order to obtain approval of a "duplicate" drug pursuant to an ANDA, the applicant must provide "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a 'listed drug')." 21 U.S.C. § 355(j)(2)(A). As defined by the FDA, "[r]eference listed drug means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application." 21 C.F.R. § 314.3. Thus, for each generic drug approved pursuant to an ANDA, a particular listed drug is identified as the "reference listed drug" or "RLD" for that generic drug.

In the ordinary course, the "RLD" will be the brand-name drug, which will have been approved pursuant to an NDA. But that is not always the case. As the FDA has explained:

> Generally, the reference listed drug will be the NDA drug product for a single source drug product. For multiple source NDA drug products or multiple source drug products without an NDA, the reference listed drug generally will be the market leader as determined by FDA on the basis of commercial data.

Abbreviated New Drug Application Regulations, 57 FR 17950-01, 17958 (2011).

---

testosterone cypionate injections (in the case of Depo-Testosterone) and 75 mg testosterone pellets (in the case of Testopel).

Thus, where there is no NDA product for a particular listed drug, the FDA may designate an RLD. This designation is based on market share, not on the procedure by which the RLD was initially approved. For this reason, the FDA terms "listed drug" and "reference listed drug" are not always equivalent to the terms NDA product or branded drug, and a drug approved through the ANDA procedure may be an RLD for future generic applications. But, significantly, the FDA regulations that govern the *labeling* of drugs use the RLD, rather than the NDA or branded drug, as the benchmark for generic labeling.

2. Federal Regulations Require that the Label for a Drug Approved Pursuant to an ANDA Be Identical to the Label for the RLD

In finding that a generic manufacturer whose product was not an RLD was prohibited from making unilateral changes to a drug label, the *Mensing* court identified several statutory and regulatory sections as sources of this prohibition. *See* 131 S. Ct. at 2574, *citing* 21 U.S.C. §§ 355(j)(2)(A)(v); § 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7); *see also* 131 S. Ct. at 2578, *citing* 21 C.F.R. § 314.150(b)(10). Examination of each of these sections in turn shows that what the law requires is that labeling for a generic drug conform to the label for the RLD, *not* the label for a "branded" or NDA drug.

Thus, 21 U.S.C. § 355(j)(2)(A)(v) requires an ANDA applicant to provide "information to show that the labeling proposed for the new drug is the same as the labeling approved for the *listed drug* referred to in clause (i). . . ." (Emphasis added.) Similarly, 21 U.S.C. § 355(j)(4)(G) permits the FDA to reject the ANDA if "information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the *listed drug* referred to in the application. . . " (Emphasis added.) FDA regulations similarly speak in terms of the referenced listed drug. Section 314.94(a)(8) requires the ANDA applicant to submit "[a] statement that the applicant's proposed labeling . . . is the same as the labeling of the *reference listed drug*. . . ." 21 C.F.R. § 314.94(a)(8) (emphasis added). Yet another provision directs the FDA to reject an ANDA where "[i]nformation submitted in the abbreviated new drug application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the *listed drug* referred to

in the abbreviated new drug application." 21 C.F.R. § 314.127 (emphasis added). Finally, FDA regulations permit the FDA to notify the applicant, and permit a hearing on a proposal to withdraw approval of an application if the agency finds "[t]hat the labeling for the drug product that is the subject of the abbreviated new drug application is no longer consistent with that for the *listed drug* referred to in the abbreviated new drug application." 21 C.F.R. § 314.150 (emphasis added).

The FDA moreover, has interpreted its regulations this way. In describing its ANDA regulations, the FDA explained that "Except for labeling differences due to exclusivity or a patent and differences under section 505(j)(2)(v) of the act, the ANDA product's labeling must be the same *as the listed drug product's labeling* because the listed drug product is the basis for ANDA approval. Consistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart." Abbreviated New Drug Application Regulations, 57 FR at 17961 (emphasis added); *see also* Brief for the United States as Amicus Curiae Supporting Respondents, *PLIVA, Inc. v. Mensing*, 2011 WL 741927 (2011) ("Amicus Brief") (quoting same). Moreover, the FDA takes the position that drug labeling must be uniform not only at the time a drug is approved, but at all times. *Mensing*, 131 S. Ct. at 2574-75. Its substitution of a drug originally approved pursuant to an ANDA as the RLD when the original NDA drug is no longer available can only be understood as a replacement for the original listed drug where regulations refer to the reference listed drug.

The Moving Defendants have not pointed to, and cannot point to, a single regulation that prohibits an RLD holder from altering the label to its drugs. Every single requirement of uniformity in labeling requires that all other generic labels be identical to the label *for the reference listed drug.* None of these regulations requires that the label for the RLD itself be identical to any other label, whether for a brand-name drug or otherwise. If no regulation prevents an RLD holder from changing its label to add additional warnings, then compliance with both state and federal duties is not impossible. Without impossibility, there is no preemption under *Mensing.* This is especially true because the regulations that permit unilateral label changes are not limited to NDA holders or brand-name manufacturers.

3. Federal Regulations Permitting Unilateral Changes to Drug Labels Are Not Limited to Manufacturers of Drugs Approved Pursuant to an NDA

Not only do the FDCA and FDA regulations require uniformity only with the label for the RLD, they also permit the RLD holder to make unilateral changes.

In the ordinary course, a drug manufacturer must use the label approved by the FDA. *Levine*, 555 U.S. at 568. In *Levine,* however, the Supreme Court found that manufacturers could unilaterally add additional warnings under certain circumstances. Because the defendant manufacturer in *Levine* could have added warnings to the label in question without FDA approval, the plaintiff was permitted to assert claims based on the manufacturer's failure to do so. Because the defendant could have strengthened the warning without violating federal law, plaintiff's state-law failure-to-warn claims were not preempted.

The regulation upon which the Supreme Court relied in finding claims for failure to warn not preempted in *Levine* permits unilateral changes (that is, without prior approval by FDA) to the label based on new information "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction. . . ." 21 C.F.R. § 314.70(c)(6)(iii)(A), *cited by Levine,* 555 U.S. at 1196; *see also Mensing,* 131 S. Ct. at 2575. (This regulation is referred to in both the *Levine* and the *Mensing* decisions as the "CBE" regulation or process.) This regulation contains no limitation on who may make the changes to the label that it describes. Rather, paragraph (6) of subsection 314.70(c) provides: "The agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, *the holder of an approved application* may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change." 21 C.F.R. § 314.70 (c)(6) (emphasis added). Changes, based on new information, that are made to add or strengthen warnings are among those described. *Id.* The relevant party, who may make such changes, is "the holder of an approved application." *Id.* Nothing in this regulation says that the approved application must have been an NDA; the holder of an approved ANDA would also meet the criterion in this section.

The holding in *Mensing* that the defendant generic manufacturer in that case could not make such changes was, therefore, not based in any way on any limitation in the CBE regulation. It was

based, instead (as, indeed, the *Mensing* opinion itself makes clear) solely on the requirements, found in the *other* regulations discussed above, that the label for a generic drug be identical to the label for the RLD. It was the need for uniformity in the label, rather than any limitation in the CBE regulation itself, that distinguished the facts of *Mensing* from those of *Levine*. Where those regulations do not impede the ability of a manufacturer to make unilateral changes, the CBE regulation expressly permits such changes to *any* holder of an approved application.

Indeed, this Court may take judicial notice that the FDA and the Pfizer Defendants' own predecessor appear to have construed the CBE regulation this way. *See* RJN ¶¶ 5-8, RJN Exhibit 3, RJN Exhibit 4. As described more fully below, *see infra* Point III, on at least two occasions, the Pfizer Defendants' predecessor submitted label changes for Depo-Testosterone to the FDA under the CBE regulation. At no time does it appear that the FDA objected to use of this process on the basis that the CBE regulation was unavailable because Depo-Testosterone was approved pursuant to an ANDA, rather than an NDA. To the extent that RLD holders such as the Pfizer Defendants (and its predecessor) and Auxilium can and do make use of the CBE process to make their own changes to the labels for their products, it is not impossible for them simultaneously to comply with state and federal regulations.

B. Depo-Testosterone and Testopel Are Each a Reference Listed Drug

As set forth in Plaintiffs' accompanying Request for Judicial Notice ("RJN"), this Court may take judicial notice that the Pfizer Defendants' TRT product, Depo-Testosterone, and Auxilium's TRT product, Testopel, are reference listed drugs. *See* RJN Exhibit 1, RJN Exhibit 2. The Moving Defendants do not contest this and indeed affirmatively state that this is so in their own Request for Judicial Notice. *See* Def. RJN ¶ 4. With respect to these drugs, as described above, the Moving Defendants' obligation is to maintain a label identical to the RLD – that is, identical to itself.

Indeed, and significantly, the Pfizer Defendants themselves have recognized that Depo-Testosterone is different from a "generic" drug. In their submission to the Judicial Panel on Multi-District Litigation opposing inclusion of claims involving Depo-Testosterone in this MDL (of which the Court may take judicial notice), the Pfizer Defendants told the JPML that Depo-Testosterone

was different from other TRT products because

> a number of generic manufacturers make injectable products containing testosterone cypionate. Some plaintiffs' medical records may identify testosterone cypionate as the product they received without also identifying the manufacturer. Therefore, in Depo-Testosterone cases, the parties will have to conduct discovery regarding product identification (i.e., who manufactured the injectable testosterone the plaintiff received), and the courts will have to entertain a variety of related summary judgment motions.

Opposition of Defendants Pfizer Inc. and Pharmacia & Upjohn Company LLC to Plaintiffs' Motions for Transfer and Coordination or Consolidation under 28 U.S.C. § 1407, *In Re: Androgel Products Liability Litigation* at 6-7, MDL No. 2545 (J.P.M.L. Apr. 30, 2014). (A copy of the Pfizer Defendants' submission to the JPML is Exhibit 5 to Plaintiffs' Request for Judicial Notice). The Pfizer Defendants went on to note that "where a plaintiff used a *generic* testosterone cypionate injection, the courts may have to entertain motions relating to whether one manufacturer can be held liable for harm caused by another manufacturer's product or whether failure-to-warn claims against generic manufacturers are preempted under *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011)." *Id.* at 7 n.5 (emphasis added). Clearly, in discussing plaintiffs who used "generic testosterone cypionate injection," the Pfizer Defendants were differentiating the product involved from their own product, Depo-Testosterone, which they did not at that time view as "generic." And, indeed, although Depo-Testosterone (and Testopel) may have been approved pursuant to ANDAs, both are "brand name" drugs.

C. *Levine,* Rather than *Mensing*, Is Controlling on the Issue of Preemption

Where, as here, the manufacturer of a generic drug is the RLD holder, *Levine,* rather than *Mensing* provides the relevant analysis and is controlling.

In *Levine*, the Supreme Court reiterated two fundamental principles of preemption jurisprudence:

> First, "the purpose of Congress is the ultimate touchstone in every pre-emption case. . . .Second, in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

555 U.S. at 565 (citations omitted). Applying these principles, the *Levine* Court rejected the argument that state law claims should be held preempted on the ground that they obstruct the purposes and objectives of federal drug labeling regulation. 555 U.S. at 573. The Court found that Congress did not intend to preempt traditional state-law remedies, noting that "[a]s it enlarged the FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs, Congress took care to preserve state law." 555 U.S. at 567 (citation omitted). The Court found, moreover, that Congress' failure to enact an express preemption provision for drugs, or to provide for a federal remedy for consumers harmed by unsafe or ineffective drugs "coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 574-75. The Court further explained:

> The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

Levine, 555 U.S. at 578-79.

The *Levine* Court also rejected the argument that failure-to-warn claims were preempted by the doctrine of impossibility. The Court acknowledged that "[t]he FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." 555 U.S. at 568. It also recognized that "[g]enerally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application." *Id.* But, it found:

> There is . . . an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is

> intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval

555 U.S. at 569. Because it was not impossible to comply with both state and federal law, the Court held, state law claims were not preempted. *Id.* at 573.

Levine is controlling here because, as demonstrated above, it is not impossible for the Moving Defendants, as RLD holders, to make unilateral changes to their labels, which are required by law only to conform to the label to the RLD itself. *Mensing*, by contrast, is distinguishable and inapplicable.

In *Mensing*, the Court found impossibility preemption because, it found, the generic manufacturer defendant could not change the label of its drug without falling afoul of federal regulations. In that case, the defendant's generic product was not the RLD; rather, the original brand-name drug remained on the market, so none of the generics had been substituted in as the RLD. *See Mensing v. Wyeth*, 562 F.Supp. 2d 1056, 1057 (D. Minn. 2008), *rev'd* 588 F.3d 603 (8th Cir. 2009), *rev'd sub nom. PLIVA v. Mensing,* 131 S.Ct. 2567 (2011). In that circumstance, the defendant was required to maintain a label identical to the label of the RLD, which was the brand-name drug. Thus, the *Mensing* Court held that the defendant was precluded by statute and FDA regulations from adding the warnings to its label that the plaintiff alleged were required under state law. 131 S. Ct. at 2577-78.[4]

Although the *Mensing* holding is clear, and rooted in the language of the FDCA and FDA regulations, the Court's language in the opinion is not always precise. In quoting the relevant

[4] The Court reiterated this holding in *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), where it found the plaintiffs' design-defect claim preempted because the claim turned on evidence that the product's label was inadequate, but the manufacturer was prohibited by federal regulations from changing the label, as set forth in *Mensing*. The Court in *Bartlett* went on to consider whether the plaintiff there could escape preemption by arguing that the defendant had been free to stop selling the product if it could not make the label sufficiently safe. *See* 133 S. Ct. at 2477-78. Plaintiffs here do not rely on a "stop selling argument," because, as demonstrated above, the Moving Defendants are not precluded from changing their label in the first place. For this reason, *Bartlett* adds little, if anything, to the analysis here.

statutory language in 21 U.S.C. § 355(j)(2)(A)(v), the Court substituted in brackets, before the word "drug" the phrase "brand name," instead of the actual word in the statute, which is "listed." 131 S. Ct. at 2574. This emendation was harmless on the facts of *Mensing*, because the brand-name drug was the listed drug, but liable to create confusion where the "listed drug" (the statutory phrase) is not the "brand name drug" (the Supreme Court's phrase). Elsewhere in the opinion, the *Mensing* Court paraphrases the relevant statutes and regulations, again substituting (without brackets) the phrase "brand name drug" for the actual statutory and regulatory text, which as quoted above consistently uses the term "listed drug." 131 S. Ct. at 2575. Paraphrasing the government's *amicus brief*, the Court again inserts the phrase "brand name," *see* 131 S. Ct. at 2575; where the brief explains that FDA "regulations require a generic drug's proposed labeling to be "the same as the labeling of the [RLD]," Amicus Brief at 15-16, the Supreme Court says that the FDA argues that changes unilaterally made to strengthen a generic drug's warning label "would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's." 131 S. Ct. at 2575, *citing* Amicus Brief at 15-16. Similarly, in a parenthetical describing relevant statutory and regulatory language, the *Mensing* Court quotes a portion of the law, but again substitutes, in brackets, the term "brand name," where the statute and regulations being cited actually say "listed drug." 131 S. Ct. at 2575, *citing* 21 U.S.C. § 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10).

The lack of precision in the language of the *Mensing* decision has led some courts astray in addressing the scope of *Mensing* preemption. The Moving Defendants note some of these cases in a footnote, *see* Moving Br. at 6 n.2, but give short shrift to the analysis contained in them, which reveals the errors that underlie their holdings. For example, in a much-cited district court decision, the court reasoned that "[a]s noted in *Mensing*, the FDA has interpreted the CBE regulations to allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated *brand name* label or to follow the FDA's instructions." *Moore v. Mylan Inc.*, 840 F.Supp.2d 1337, 1347 (N.D. Ga. 2012) (emphasis added). This, of course, was a mis-statement of the FDA's actual interpretation of its regulations, which is only that a generic label must at all times be identical to the RLD label. But, based on this misapprehension of FDA regulations, the *Moore* court believed

the issue before it was whether the RLD holder in that case it had acquired "the same rights and obligations as a 'brand-name' manufacturer"; finding no source for the acquisition of such rights, the court rejected the argument that an RLD holder is situated differently from the manufacturer of a generic drug that is not the RLD. *Id.* at 1348. The district court in *Hogue v. Pfizer, Inc.*, 2012 WL 11944897, *3 (S.D. Ohio Sept. 27, 2012), similarly quoted *Mensing* as holding that "the FDA interprets the CBE process to allow generic manufacturers to change generic drug labels only "to match an updated brand-name label or to follow the FDA's instructions" and thus misapprehended the actual scope of FDA regulations.[5]

The district court in *Morris v. Wyeth, Inc.*, 2012 WL 601455 (W.D. La. Feb. 23, 2012), citing *Moore*, similarly misapprehended the issue. The *Morris* court thought the question was whether "the FDA considered TEVA to be a brand name manufacturer with the requisite duty to unilaterally change its product's labeling simply because the FDA designated TEVA's metoclopramide as the RLD." 2012 WL 601455, *6. But the *duty* to unilaterally change the label arises under *state* law, not under federal law or FDA regulations. It was the *inability* to carry out that state-law duty, because of FDA regulations, that led to the impossibility preemption in *Mensing*. The *Morris* court, like the

[5] The *Hogue* court also cited a 2007 FDA determination that the court stated "expressly recognized the RLD designation does nothing to alter an ANDA holder's duties concerning labeling changes," 2012 WL 11944897, *4, *citing Determination That Brethine (Terbutaline Sulfate) Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness*, 72 Fed. Reg. 39629–01, 2007 WL 2047956 (July 19, 2007) ("Brethine Determination"), but the Brethine Determination contains no such recognition, express or otherwise. In the Brethine Determination, the FDA determined that the brand-name drug, Brethine (terbutaline sulfate) injection, which was no longer on the market, had not been removed from the market for reasons of safety or effectiveness. This determination was necessary before a generic version could be approved. After determining that an ANDA could proceed, because the drug had not been withdrawn for reasons of safety or effectiveness, the FDA further noted: "If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling." Brethine Determination, 72 Fed. Reg. at 39630. That FDA would notify applicants if it required label changes in no way demonstrates (and certainly does not "expressly recognize[]," as the *Hogue* court believed) that after approval, an RLD holder would be precluded from making unilateral changes to a label to reflect updated safety information.

Moore court, ought to have considered whether FDA regulations prohibit an RLD holder from making the requisite changes to the label, not whether such regulations *require* it to do so.

The only Court of Appeals decision of which Plaintiffs are aware to address this issue followed *Moore* and *Morris* and reached the same erroneous conclusion. *See In Re Darvocet, Darvon, and Propoxyphene Products Liability Litigation*, 756 F.3d 917 (6th Cir. 2014). That court also cited a footnote in a 2013 FDA Guidance, but misunderstood the significance of the language it quoted. *See* 756 F.3d at 933, *citing* FDA, Center for Drug Evaluation and Research, Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD & C Act, at 7 n. 10 (July 2013) ("FDA 2013 Guidance"), available at http://1.usa.gov/1cF0bdk. The *Darvocet* court quoted the 2013 Guidance as saying:

> Under existing FDA regulations, ANDA holders cannot make labeling changes through the formal supplement process under 21 CFR 314.70 *in all circumstances in which NDA holders can* because an ANDA's labeling must be the same as the NDA RLD's labeling (with some exceptions, as described in 21 CFR 314.94(a)(8)(iv)). Accordingly, the changes-being-effected supplement process under 21 CFR 314.70(c) is not expressly available to ANDA holders except to match the RLD labeling or to respond to FDA's specific request to submit a labeling change under this provision.

756 F.3d at 933, citing FDA 2013 Guidance at 7 n.10 (emphasis added). But the *Darvocet* court ignored entirely the emphasized words limiting the scope of the FDA's comment to the situation in which there is an NDA holder that *can* make labelling changes. Because it used the NDA/ANDA distinction, rather than the "listed drug" terminology of the regulations, the FDA had to qualify its statement about the ability of an ANDA holder to make changes to make clear that this was only true when the ANDA holder is *not* the RLD holder – that is, when there is an NDA holder that can make changes to the label. The *Darvocet* court failed to appreciate this qualification or its basis in the language of the FDA regulations themselves. Although the language in the FDA 2013 Guidance could have been clearer, it is important to note that the issue was addressed only in a footnote, which presumably received less attention to the precision of the wording than the issues more

thoroughly addressed in the Guidance.[6]

In contrast to these court decisions, based on an erroneous reading of *Mensing* and FDA regulations, the decision of an appellate court in Pennsylvania in *In re Reglan/Metoclopramide Litigation*, 74 A.3d 221 (Pa. Super. 2013), is insightful and persuasive in finding that claims against an RLD holder are not preempted. The *Reglan* court recognized, as the other decisions discussed above did not, that "our resolution of the issue of whether impossibility pre-emption applies to [defendant] hinges on whether that entity, as the RLD holder, had the ability under federal law to change or update its label." 74 A.2d at 224. The *Reglan* court then parsed through the actual FDA regulations at issue. It noted, as other courts had not, that the so-called "CBE regulation," which permits unilateral changes to the label and on which the Supreme Court relied in *Levine* "did not contain the terms 'brand name' and 'generic.'" 74 A.2d at 225. Rather, it correctly noted:

> [T]he regulations refer to the "applicant" seeking to change the label to "add or strengthen a contraindication, warning, precaution or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product" and who could make the labeling change upon filing its supplemental application with the FDA.

Id. at 225-226. Thus, the court realized that the CBE regulation was not, by its terms, limited to brand-name manufacturers or NDA holders. The *Reglan* court also noticed what other courts had failed to see: that "the *Mensing* Court referred to RLD holders and brand-name manufacturers interchangeably in its opinion. In fact, the *Mensing* Court inserted the language 'the brand-name' when quoting regulations employing the term 'listed drug'. . . ." *Id.* at 226. Thus, the *Reglan* court

[6] The Moving Defendants also cite *Cooper v. Wyeth, Inc.*, 2012 WL 733846 (M.D. La. Mar. 6, 2012), but *Cooper* is no more helpful to their position. In *Cooper,* the plaintiff argued that one of the defendants was an RLD holder for one particular form of the drug at issue, *but not for the form the plaintiff ingested.* 2012 WL 733846, *7-8. Because the defendant was required to use a label identical to the label for the RLD for that form of the drug, the facts of the case fell within the *Mensing* holding, rather than the *Levine* holding. The *Cooper* court also relied on the Brethine Determination for its conclusion that RLD holders may not make changes to the labels for their drugs, *see id.* at *8; for the reasons discussed above, *see supra* n.3, this reliance was erroneous, as the Brethine Determination does not address the issue that was before the *Cooper* court and before this Court.

reasoned:

> In our examination of the regulations regarding the CBE process, we find no indication that only brand-name manufacturers that obtained NDA approval, rather than RLDs generally, can utilize the process. If the CBE process is available only to the original NDA/RLD holder, there would be no need to designate a successor RLD in a situation where the original RLD withdraws its drug. Generic manufacturers could continue to file ANDAs demonstrating that their proposed generic drugs are equivalent to that of the obsolete NDA/RLD, but no manufacturer would bear any responsibility for the content of the label or the continued safety and efficacy of the drug. The purpose for designating a successor RLD is to have a standard to which subsequent ANDAs must correspond. This includes labeling.

74 A.2d at 227.

Finally, in finding plaintiffs' claims in *Reglan* not preempted, the Pennsylvania court noted that it was the defendant that had the burden of proof on the issue of preemption. Thus, the court explained, "Herein, we have a generic RLD seeking to avoid liability under the *Mensing* rationale. The burden of proving the basis for the pre-emption defense rests with [defendant], and *it has not established with the requisite certainty* that it was impossible to modify its label." *Id.* (emphasis added). In this conclusion, the *Reglan* court echoed the language of the Supreme Court in *Levine* that "[i]mpossibility pre-emption is a demanding defense" and that "[o]n the record before us, [defendant] has failed to demonstrate that it was impossible for it to comply with both federal and state requirements." 555 U.S. at 572.

This Court should follow *Reglan* and apply the Supreme Court's analysis in *Levine* to find that plaintiffs' claims here are not preempted because, as RLD holders, the Moving Defendants have not demonstrated that they were precluded from making changes to the labels of their TRT products in order to strengthen the warnings on those labels. Rather, under FDA regulations, the Moving Defendants were required only to maintain labels identical to the label of the RLD; changes to their own labels would not result in divergence from the label of the RLD where their drugs are the RLDs and would not interfere with the uniformity the FDA seeks to maintain. This reasoning applies with equal force to Plaintiffs' claims for failure to warn, for design defect, negligence, breach of warranty, misrepresentation and fraud, redhibition, consumer protection, and unjust enrichment,

all of which flow, to some extent from the Moving Defendants' failure to provide adequate warnings of the dangers associated with their TRT products. Indeed, the Moving Defendants themselves recognize that their preemption argument is the same with respect to all of Plaintiffs' claims. *See* Moving Br. at 14. If the failure to warn claim is not preempted – as Plaintiffs have demonstrated – the other claims are similarly not preempted. For this reason, this Court should deny the Moving Defendants' motion to dismiss on grounds of *Mensing/Bartlett* preemption in its entirety.[7]

D. *Buckman* Preemption Is Inapplicable

The Moving Defendants make two arguments that Plaintiffs' claims are preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), but neither is correct.

First, the Moving Defendants contend that any claim of fraud on the FDA is preempted. *See* Moving Br. at 21. But Plaintiffs assert no *claim* for fraud on the FDA. Plaintiffs do assert that such fraud occurred – but this Court has already held that such allegations are proper. *See In re Testosterone Replacement Therapy Products Liab. Litig.,* No. 14 C 1748, 2014 WL 7365872, *13 (N.D. Ill. Dec. 23, 2014) (the "December 2014 Ruling"). In the December 2014 ruling, this Court held that a Michigan statute that insulates from liability manufacturers of drugs approved by the FDA did not require dismissal of the claims of Michigan plaintiffs, because the statute created an exception for situations where there had been fraud on the FDA. Defendants argued that this exception to the defense under the statute was preempted, because, they contended, Plaintiffs were barred, under *Buckman*, from proving fraud on the FDA. This Court rejected that argument and concluded that the exception to the defense was not preempted. It held:

> If Montgomery and other plaintiffs whose claims are governed by Michigan law can, consistent with Federal Rule of Civil Procedure 11(b), plausibly allege that the defendants intentionally withheld or misrepresented information to the FDA in a

[7] The Moving Defendants argue that Plaintiffs' allegations concerning off-label marketing and promotion do not save their claims from *Mensing* preemption. *See* Moving Br. at 16. As discussed above, Plaintiffs' claims are not preempted under *Mensing* and so do not require "saving." Plaintiffs do not understand the Moving Defendants to be arguing that the allegations of off-label promotion and marketing give rise to a separate basis for preemption beyond the impossibility preemption found in *Mensing* and *Bartlett*.

> way that affected the agency's approval of the drug, their cases will be permitted to proceed.

2014 WL 7365872, *8. This is precisely what Plaintiffs have done. Defendants offer no new arguments why the Court's December 2014 Ruling was incorrect or should be re-visited. Indeed, they do not acknowledge that the issue has already been addressed. Because this Court has already ruled that Plaintiffs' "fraud on the FDA" allegations are not preempted and are proper – indeed, required in order to proceed under Michigan law – the Moving Defendants' continued argument to the contrary should be rejected.

The Moving Defendants also claim that Plaintiffs' allegations concerning off-label promotion and marketing seek improperly to enforce the FDCA and are preempted by *Buckman*. *See* Moving Br. at 19-21. This is nonsense: only *claims*, not allegations, may be preempted. Indeed, the Court in *Buckman* explicitly stated that what was preempted were *claims* arising solely from fraud on the FDA, rather than any use of evidence of fraud on the FDA, holding:

> [T]he plaintiffs' state-law fraud-on-the-FDA *claims* conflict with, and are therefore impliedly pre-empted by, federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA *claims* under state tort law.

Id. at 348 (emphasis added) (citation omitted). As courts interpreting *Buckman* have noticed, "the plaintiffs in *Buckman* alleged no state-law claim and were concerned exclusively with alleged fraud on the FDA that had occurred as part of that approval process." *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1232-33 (9th Cir. 2013) (*en banc*); *accord Desiano v. Warner-Lambert & Co.*, 467 F.3d 85. 95 (2d Cir. 2006), ("In *Buckman*, there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements."), *aff'd sub nom. Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008). *Buckman* thus stands only for the proposition that claims arising solely from a defendant's alleged fraud on the FDA are preempted. It leaves traditional state law claims untouched, even where evidence of fraud on the FDA is introduced to support such claims.

If allegations of fraud on the FDA are not preempted under *Buckman*, it follows even more strongly that allegations of off-label marketing and promotion are similarly not preempted, as Plaintiffs are no more seeking to enforce FDA's rules concerning off-label promotion than they are seeking to enforce FDA's prohibitions on fraud. Not one of Plaintiffs' claims alleges that Defendants are liable solely on account of off-label promotion or marketing; all of the claims are traditional state law tort claims of the kind preserved under *Buckman*.

Defendants insist that, no matter how styled, Plaintiffs' allegations concerning off-label promotion must be an attempt to enforce the FDCA or FDA regulations, but this is demonstrably false. What Plaintiffs allege is that the Moving Defendants' off-label promotion and marketing exacerbated their inadequate warnings. As the Moving Defendants well know, the decision to prescribe a drug requires a balancing of the benefits of the drug for the particular patient against the risks of the drug to that patient. Where the manufacturer fails to warn of certain risks, the balance cannot be properly performed. If an inadequate warning is provided and the benefits of the drug are also exaggerated, the balance is similarly distorted and warnings that might be adequate in the context of the true benefits of the drug become inadequate as compared to the invented or exaggerated benefits. An extreme example of this can be seen in the case of certain especially toxic drugs used to treat cancer. The horrific side effects of such drugs may be a reasonable price to pay if the alternative is almost certain death from cancer, but no one would take such toxic drugs to ward off a cold. The adequacy of the warning of the side effects of a drug can only be assessed in the context of accurate information about the true benefits of the drug.

The same is true here. Because defendants exaggerated the benefits of their TRT products, the risks of heart attacks and strokes associated with such products could not properly be assessed or warned about; any warnings that were given were improperly diluted by claims of benefits that the Moving Defendants had no basis to believe existed. The problem with off-label promotion is not only, or even primarily, that it violates FDA regulations. The problem with off-label promotion is that the drug has not been shown to be effective for the benefits touted by the manufacturer. Lacking evidence of efficacy for off-label uses, the manufacturer inevitably distorts its warnings by

claiming the product can treat conditions for which it has not been shown to be safe or effective. Plaintiffs' allegations concerning off-label promotion are part and parcel of their failure to warn claims, not an attempt to enforce FDA regulations. They are not preempted under *Buckman*.

II. THIS COURT SHOULD PERMIT PLAINTIFFS TO TAKE DISCOVERY WITH RESPECT TO LABEL CHANGES THE MOVING DEFENDANT HAVE MADE SINCE THE TIME THEIR TRT PRODUCTS WERE APPROVED

To the extent there is any uncertainty about the extent to which the Moving Defendants may make unilateral changes to their labels because their drugs are RLDs, this Court should deny the motion to dismiss in order to permit Plaintiffs to establish in discovery that these defendants have in fact made unilateral changes to their labels, precisely as Plaintiffs believe they are entitled to do.

Although the Moving Defendants claim the "only conceivable factual issue is whether ANDA Defendants' TRT products are indeed generic medications," *see* Moving Br. at 22, as discussed above, the actual question at issue is whether the Moving Defendants are permitted to change their labels. Although, as discussed above, this is primarily a legal question, it may also be demonstrated by facts confirming that a previous RLD holder for Depo-Testosterone actually made such unilateral changes to the label Depo-Testosterone label, even though those products were originally approved through ANDAs, rather than NDAs. Plaintiffs are aware of at least two instances where this appears to have occurred, *see* RJN ¶¶ 5-8, RJN Exhibit 3, RJN Exhibit 4, but discovery would be required to investigate fully these label changes and others like them that may have occurred, as well as the FDA's response to them. If in fact the Moving Defendants have changed their labels in precisely the way Plaintiffs contend they may, and if the FDA has confirmed that such changes are permitted, the Moving Defendants' would be precluded from arguing that they are unable to do what state law requires them to do.

In addition, as set forth in the Second Amended Master Long-Form Complaint ("Complaint"), both Depo-Testosterone and Testopel were approved prior to the enactment of the Hatch-Waxman Amendments in 1984. *See* Complaint ¶¶ 83 (Testopel approved in 1972), 85 (Depo-Testosterone approved in 1979). At that time, there was no requirement that the label of the generic

be identical to the label of the listed drug. If the manufacturers of these products knew or should have known of the need to change their label prior to the enactment of Hatch-Waxman, but such changes were never made, then preemption would similarly not apply, because federal law did not prevent the Moving Defendants from complying with their state law duties to warn. *See supra* Point I. The facts necessarily to establish that any of the Moving Defendants knew or should have known, prior to the enactment of Hatch-Waxman, that the label for their TRT products was inadequate to warn sufficiently of the dangers of the drug, are outside the pleadings here, such that the Court cannot determine, on the record before it, that Plaintiffs' claims are necessarily preempted.[8]

III. PLAINTIFFS' OFF-LABEL MARKETING AND PROMOTION ALLEGATIONS AGAINST THE ACTAVIS DEFENDANTS ARE SUFFICIENTLY PLED

The Moving Defendants claim that, whether preempted or not, Plaintiffs' allegations concerning off-label marketing and promotion are inadequately pled. *See* Moving Br. at 17-18.[9] But

[8] It should be noted that the factual issues described here would not render preemption meaningless in the ordinary case. First, as described above, this Court can take judicial notice that the Moving Defendants' TRT products are RLDs. Second, this Court can take judicial notice that some RLD holders appear to have unilateral changes to the label for TRT products, even though those products were approved pursuant to an ANDA. Third, as noted above, and as pleaded in the Complaint, some of the Moving Defendants' TRT products were approved prior to the enactment of the Hatch-Waxman amendments. These facts ensure that the exception to preemption Plaintiffs believe applies here is not so broad as to nullify preemption or the holding of *Mensing* generally.

[9] The Moving Defendants also claim that Plaintiffs' design defect claims are inadequately pled, but provide no explanation why this is so. After describing Plaintiffs' design defect allegations, the entirety of the Moving Defendants' contention on this point consists of a single conclusory sentence: "Those allegations do not satisfy plaintiffs' pleading requirements under *Ashcroft v. Ibal*, 556 U.S. 662, 678 (2009), and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2008)." The Moving Defendants identify no details that are missing or otherwise explain why they believe Plaintiffs' allegations are insufficient. Nor are they correct. To begin with, the allegations quoted by the Moving Defendants are only the summation of Plaintiffs' design defect claims; the Moving Defendants ignore the numerous detailed allegations in the Complaint about the dangers of their TRT products and the serious health risks these products present. *See, e.g.,* Complaint ¶¶ 391-393, 405, 413-416, 423, 473, 474. These allegations identify the specific harms caused by the Moving Defendants' TRT products. For example, in a paragraph curiously omitted by the Moving Defendants (who cite the preceding and following paragraphs, but seem not to have noticed the one in between), Plaintiffs allege that "The design of each of AndroGel, Axiron, Fortesta, Delatestryl, (footnote continues on next page)

they do not identify a single one of Plaintiffs' causes of action that fails to state a claim for relief as a result of this purported defect. As discussed above, Plaintiffs do not seek to enforce FDA regulations concerning off-label promotion and assert no claim grounded solely in such activities. Plaintiffs' allegations concerning off-label marketing and promotion relate to, and provide additional grounds for, their claims regarding the Moving Defendants' failure to warn (whether under a strict liability or a negligence standard), as well as Plaintiffs' claims sounding in breach of warranty, fraud, misrepresentation, redhibition, deceptive practices, or unjust enrichment. In that context, the allegations concerning off-label marketing and promotion provide additional facts that strengthen the other detailed allegations supporting each and every one of these claims, each of which is sufficient to state a claim for relief based on the totality of Plaintiffs' allegations. For this reason, the Moving Defendants' citation to *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) is wholly inapposite. Nothing in *Iqbal* (or any other authority of which Plaintiffs are aware) provides a basis for the Court to assess the sufficiency of a plaintiff's allegations other than with reference to the claims for relief asserted. Nothing in Rule 12(b)(6), moreover, authorizes a court to dismiss "allegations," rather than claims.

Testim, Testopel, Striant, Depo-Testosterone, and Androderm was defective and unsafe *in that each caused serious injuries and death as the result of the formation of blood clots and adverse cardiovascular events, including but not limited to deep vein thrombosis, pulmonary embolism, stroke, ischemic injuries, infarctions, coronary heart failure, and cardiovascular disease*." Complaint at ¶ 474 (emphasis added); *compare* Moving Br. at 12 (quoting ¶¶ 473, 475). To the extent that the Moving Defendants' quarrel with the allegations of design defect is that they "include[] rote allegations," *see* Moving Br. at 12, the argument should be rejected. The issue is not whether Plaintiffs have pleaded their conclusions, the issue is whether they have pleaded *nothing more* than their conclusions. As the paragraphs noted show, Plaintiffs here have pleaded far more than conclusory statements of defect: they have sufficiently identified the defects of which they complain.

CONCLUSION

For the foregoing reasons, this Court should deny in its entirety the Moving Defendants' motion to dismiss.

Dated: June 15, 2015

Respectfully submitted,

/s/ Trent B. Miracle

Trent B. Miracle
SIMMONS HANLY CONROY
One Court Street
Alton, IL 62002
Phone: (618) 259-2222
Fax: (618) 259-2252
Email: tmiracle@simmonsfirm.com

Ronald Johnson, Jr.
SCHACHTER, HENDY & JOHNSON PSC
909 Wrights Summit Parkway, Suite 210
Ft. Wright, KY 41011
Phone: (859) 578-4444
Fax: (859) 578-4440
Email: rjohnson@pschacter.com

Christopher A. Seeger
SEEGER WEISS LLP
77 Water Street
New York, NY 10005
Phone: (212) 584-0700
Fax: (212) 584-0799
Email: cseeger@seegerweiss.com

Plaintiffs' Co-Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that on June 15, 2015, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Trent B. Miracle
Trent B. Miracle